and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(b) These officials may not further redelegate this authority.

§ 5.411 Medical device recall authority.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360h(e)), which have been delegated to the Commissioner of Food and Drugs:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.412 Temporary suspension of a medical device application.

(a) The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(e)), to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy Directors, Office of Device Evaluation, CDRH.

(4) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(5) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Directors, Office of Compliance and Biologics Quality, CBER.

(b) These officials may not further redelegate this authority.

§ 5.413 Approval, disapproval, or withdrawal of approval of applications and entering into agreements for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)):

(1) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance, CDRH.

(2) The Director and Deputy Directors, Center for Biologics Evaluation